- INSTRUCTIONS FOR USE -

[IFU]

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1] INTRODUCTION

The **Sherlock** catheter tip location detector is designed to aid in the placement of central venous catheters by providing real-time catheter tip location information relative to external physical landmarks. It is designed to operate with Bard Access Systems kits labeled, "with **Sherlock**" Tip Location Stylet.

2] Description

The **Sherlock** detector consists of the following components:

- **Sherlock** Sensor Module
- **Sherlock** Screen Module
- AC adaptor and power cord
- Carrying Case
- **Sherlock** Stylet [included with specially marked central venous catheter kits]
- Sensor Holder Pouch [included with specially marked central venous catheter kits]

The **Sherlock** detector is packaged in its own carrying case with the sensor module, screen module and AC adaptor and power cord. The sensor module is a small, remotely powered detector that is permanently attached to an extension cable. It is designed to track catheter tip movement, detect catheter tip orientation,

and sense the catheter tip end point. The **Sherlock** detector may be placed over the right third intercostal space as recommended by the 1998 AVA Position Statement, although external measurements can never exactly represent the internal venous anatomy. The extension cable connects the sensor module to the screen module. The screen module is a hand-held, battery-operated instrument that illustrates the location and direction of the specialized magnetic stylet tip as it passes under the sensor. This special stylet is only located in Bard Access Systems central venous catheter kits "with **Sherlock**" Tip Location Stylet. Both audio and visual cues are presented to the clinician.

The AC adaptor charges the internal system battery located in the screen module. The detector can be powered by the internal battery or the external power supply. The **Sherlock** stylet and sensor holder pouch are single-use items and are packaged with Bard Access Systems central venous catheters intended to be used only with the **Sherlock** catheter tip location detector.

No magnetic energy is generated by the screen or sensor module. Permanent magnets are encapsulated within the tip of the **Sherlock** stylet. As the stylet is advanced under the sensor module, the module detects the magnetic field that is generated by the stylet. The position and direction of the stylet tip is calculated and then displayed on the screen module.

Note: The **Sherlock** detector can be used on patients who have implanted cardiac rhythm devices such as pacemakers and defibrillators. When a cardiac rhythm device is present, it is recommended that the **Sherlock** tip location system stylet be placed on the contralateral side.

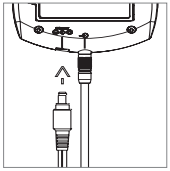
This booklet describes the controls, information displays, and proper use of the **Sherlock** catheter tip location detector. Insertion instructions for catheters incorporating **Sherlock** stylets are packaged with the Bard Access Systems catheter kits and should be consulted on an individual basis.

Components

Sherlock Detector

Sensor Module

Screen Module



Detector with AC adapter inserted

AC Adaptor and Power Cord

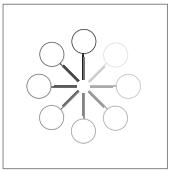
Sherlock Carrying Case. The carrying case can be attached to the Site~Rite* roll stand basket using the straps provided on the rear of the carrying case.

Display Screen Information

Start-up Screen

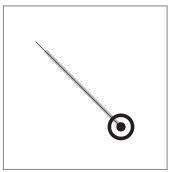
Start/Calibration

Sensor Module Unplugged

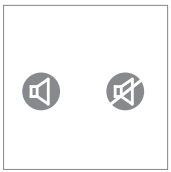


Calibrating

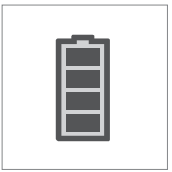
Ready for Use



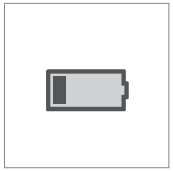
Stylet Tip Position



Mute/No Mute



Battery Charge



Low Battery

Magnetic Error

Repair Needed

3] Indications For Use

The **Sherlock** Tip Location System (TLS) detector quickly locates and confirms the position of specially designed, magnet-tipped Peripherally Inserted Central Catheters [PICCs] and Central Venous Catheters [CVCs] during initial placement. This device may be used by appropriate caregivers in hospitals, long-term care facilities or home-care settings.

The **Sherlock** Tip Location System (TLS) detector provides rapid feedback to the caregiver, but was not designed to replace conventional methods of placement verification. Users are urged to confirm correct placement according to their established institutional protocol and clinical judgment.

Note: Use of the **Sherlock** detector is not recommended with catheters that are not specifically marked with the **Sherlock** catheter tip location system trademark and logo, and manufactured by Bard Access Systems.

4] Warnings / Precautions

Warnings

DANGER: Do not operate the **Sherlock** detector in the presence of flammable anesthetic gases – potential explosion hazard.

Precautions

1 - Federal [U.S.A.] law restricts this detector to sale by or on the order of a physician.
2 - Do not submerge the **Sherlock** sensor or screen in water or other fluids.
3 - Do not attempt to sterilize.
4 - The **Sherlock** sensor and screen must only be used with Bard Access Systems central venous catheters that contain the **Sherlock** stylet.
5 - Wired undergarments may affect the performance of the **Sherlock** detector.
6 - Avoid contact between the **Sherlock** sensor module and strong magnetic fields such as MRIs.

7 - Do not allow any ferromagnetic objects, e.g. metal instruments, watches, jewelry, electronic detectors, metal bedrails, etc. to be within 30 cm [12 in] of the **Sherlock** sensor module once the calibration process is complete. The sensor module may detect the item's magnetic field, which will interfere with the sensor module's ability to accurately locate the **Sherlock** stylet tip.

8 - Active electric motor driven equipment, such as pumps should not be used within five feet of the **Sherlock** sensor module during the catheter insertion procedure as they may interfere with **Sherlock**'s detection of the stylet.

9 - Temporary disruption of the cardiac rhythm device may occur if the **Sherlock** tip location stylet passes within 1 cm of the cardiac rhythm device. Use care if placing the **Sherlock** tip location stylet on the same side as the cardiac rhythm device.

Note: A final confirmation of the catheter tip location must still be determined based on the protocol of the facility.

Possible Complications

- Ferromagnetic interference
- Temporary disruption of cardiac rhythm devices
- Sensor or screen malfunction

Complications associated with central venous catheter placements. For possible complications consult Bard Access Systems catheter "Instructions for Use".

5] Service and Information

For questions regarding service please call Bard Access Systems at 1-800-545-0890.

The **Sherlock** detector contains no user serviceable parts. Only Bard Access Systems authorized service personnel should attempt to service this equipment.

Note: Servicing of the battery pack or the combination AC adaptor must be performed only by Bard Access Systems authorized service personnel.

The following actions void the warranty of the **Sherlock** detector:

- Opening or attempting to open the **Sherlock** sensor or screen modules.
- Removal of system labels by anyone other than by Bard Access Systems authorized service personnel.
- Opening or attempting to open the **Sherlock** battery pack or the combination AC adaptor.
- Connecting the **Sherlock** screen module to any power source other than the **Sherlock** combination AC adaptor and battery pack.
- Connecting the **Sherlock** screen module to any AC adaptor other than the one provided with the detector.
- Connecting the **Sherlock** detector to any unauthorized accessory.

6] Instructions For Use

Note: Prior to use of the **Sherlock** detector, the operator must read these instructions and be thoroughly familiar with the **Sherlock** detector operation.

Step 1: Patient Preparation

1 - Ensure your Bard Access Systems catheter kit contains the **Sherlock** stylet.

2 - Inspect the **Sherlock** screen and sensor modules for damage prior to use. If damage to the **Sherlock** detector is noted, do not use it.

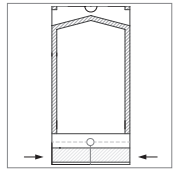
3 - Ensure there is sufficient battery life to perform procedure prior to beginning procedure. If not, the device can be used with the AC adapter by plugging the AC adapter into the screen module.

4 - Lower the bedrail on the insertion side.

5 - Position the patient for the procedure.

6 - Open the sensor holder pouch and insert the sensor.

7 - Secure the sensor in the pouch using the adhesive tabs on the bottom of the pouch.



8 - Identify desired location on the patient's body to place the **Sherlock** sensor.

a - The **Sherlock** sensor may be placed over the right intercostal space to track catheter tip movement, detect catheter tip orientation, and sense the catheter tip end point relative to this external landmark.

Note: The external measurement can never exactly represent the internal venous anatomy. Consider patient body habitus, making adjustments in catheter length for extremes in body weight and / or height.

b - Alternatively, the **Sherlock** sensor may be placed along the right clavicle to track catheter movement and detect catheter tip orientation during placement.

9 - Follow facility protocols for locating the anatomical landmark on the patient's chest.

Note: The **Sherlock** sensor will work for either left-sided or right-sided placement procedures.

Note: Although the **Sherlock** sensor may be used external to the patient's gown, for best results, the pouched sensor module should be placed directly on the patient's skin. To provide secure attachment, clean skin if necessary. Excessive hair should be removed if possible.

10 - Remove the adhesive backing from the back of the sensor holder pouch.

11 - Place the sensor module over the selected anatomical landmark on the patient. Use the **Sherlock** logo on the lower third of the sensor module to mark the anatomical landmark. A picture of the sensor module with the **Sherlock** logo is displayed on the screen module and can be used as a reference during the catheter placement procedure.

Note: The sensor module's cable should be directed towards the patient's feet.

12 - Securely attach the sensor module to the patient with adhesive side down. Press down on the **Sherlock** sensor module firmly to allow for the adhesive strips to adhere.

Note: Do not move the **Sherlock** sensor module after it is secure. **Best results will be achieved if the patient remains still** and the sensor module is not placed on open wounds, over bandages, drapes, gowns, or other coverings.

13 - Connect the **Sherlock** sensor module cable to the **Sherlock** screen module. To connect the cable to the screen module align the red dot on both the cable connector and the screen module connector and gently push. You will feel the connectors snap together.

14 - Place the **Sherlock** screen module outside the sterile field where the screen module may be conveniently and easily viewed by the user during catheter placement.

15 - Set-up sterile field.

16 - Prepare the insertion site with ChloraPrep One-Step Applicator or according to institutional policy using sterile technique.

Step 2: Sherlock Device Preparation

1 - Power on the **Sherlock** detector by pressing and holding the on-off button. While the detector is powering on, the screen module will flash the **Sherlock** logo and the screen will illuminate.

2 - Allow the **Sherlock** detector to complete its power on cycle. This cycle will take approximately 5 seconds. The screen will display the "Start/Calibration" icon when the system is ready for use.

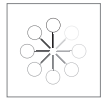
Note: If the indicator for low battery [flashing battery icon] is displayed, battery power is low and the AC adaptor should be used during catheter placement by plugging the AC adapter into the screen module. The **Sherlock** detector can be used for approximately 20 minutes on battery power after the low battery indicator is first displayed.

Step 3: Catheter Placement and Determination of Tip Position

1 - Press the "Start/Calibration" button on the **Sherlock** screen module.

Note: During the calibration sequence ensure that the Bard Access Systems stylet is at least 30 cm [12 in] away from the sensor module.

Note: If the unplugged sensor module is displayed, plug the sensor module into the screen module. Press the "Start/Calibration" button to begin calibration.



2 - The **Sherlock** detector will calibrate itself. During the calibration process the screen will display a rotating magnifying glass. When the **Sherlock** detector is ready for use, the sensor module outline is displayed.

3 - Once the calibration process is complete, **do not reposition the patient** [e.g. move patient up or down, elevate or lower bed, raise or lower bedrails, etc.]. **Ask the patient to remain still.**

Caution: Do not allow any ferromagnetic objects, e.g. metal instruments, watches, jewelry, electronic detectors, metal bedrails, etc. to be within 30 cm [12 in] of the **Sherlock** sensor module once the calibration process is complete. The sensor module may detect the item's magnetic field, which will interfere with the sensor module's ability to accurately locate the **Sherlock** stylet tip.

Caution: Active electric motor driven equipment, such as pumps, should not be used within five feet of the **Sherlock** sensor module during the procedure. The **Sherlock** detector should never be used in or near a room containing MRI equipment.

4 - Remove and discard skin prep gloves.

5 - Continue patient preparation and establish sterile field according to catheter instructions for use and facility protocol.

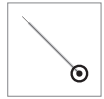
6 - Insert the catheter with the preloaded **Sherlock** stylet according to the Bard Access Systems catheter's instructions for use.

Note for open-ended, polyurethane catheters: Follow the instructions for use in the Bard Access Systems **Sherlock**-labeled catheter kits to assure the tip of the **Sherlock** stylet is not trimmed and is within 1 cm of the end of the catheter prior to catheter insertion. If the magnetic tip of the **Sherlock** stylet is accidentaly removed by trimming, the stylet cannot be detected by the **Sherlock** detector.

7 - As the stylet tip approaches the **Sherlock** sensor module, an icon indicates where the stylet tip is located in relation to the sensor module. The location icon is displayed in its relative position to the sensor module, as if viewed from above and through the sensor module into the patient.

Note: The **Sherlock** detector can detect the **Sherlock** magnet-tipped stylet while it is still outside the physical perimeter of the sensor module. In this case, the stylet location icon will be an arrow at the edge of the display, pointing towards the location of the approaching stylet.

Note: When the stylet tip is positioned underneath the **Sherlock** sensor module, the stylet location icon changes to a representation of the stylet tip, and indicates the location and orientation of the stylet tip beneath the sensor module.



8 - In the event the stylet icon does not appear on the **Sherlock** screen module after the pre-measured length of the catheter has been inserted, pull the catheter back 20-25 cm and reinsert. If the stylet icon is still not visible after attempted reinsertion, the device may need to be recalibrated.

a - Withdraw the catheter at least 30 cm; this may require removing the catheter from the introducer sheath.

b - Press the "Start/Calibration" button to begin calibration.

c - Once the calibration process is complete, **do not reposition the patient. Ask the patient to remain still.**

d - Don a new pair of sterile gloves.

e - Reinsert the catheter and stylet. As the stylet tip approaches the **Sherlock** sensor module, the cursor will indicate where the stylet tip is located in relation to the sensor module.

9 - If the icon does not appear on the **Sherlock** screen module after attempted recalibration and reinsertion, the **Sherlock** sensor module can be placed along the clavicle to provide feedback on the catheter path during placement.

a - Retract the catheter so that the tip of the stylet is at least 30 cm [12 in] away from the sensor module. This may require removing the catheter from the introducer sheath.
b - Remove sterile drapes from patient's chest while maintaining sterile insertion site.
c - Remove the sensor holder pouch from the patient and remove the sensor module from the pouch.
d - Dispose of the sensor holder pouch in accordance with facility policy.
e - Place the sensor in the second sensor holder pouch provided in catheter kits containing the **Sherlock** stylet. Secure the sensor in the pouch using the adhesive tabs on the bottom of the pouch.
f - Remove the adhesive backing from the back of the sensor holder pouch.
g - Place the sensor module over the clavicle on the same side as attempted catheter placement.
h - Securely attach the sensor module to the patient with adhesive side down. Press down on the **Sherlock** sensor module firmly to allow for the adhesive strips to adhere.
i - Press the "Start/Calibration" button to begin calibration.
j - Once the calibration process is complete, **do not reposition the patient. Ask the patient to remain still.**
k - Don a new pair of sterile gloves.
l - Re-establish sterile field, according to catheter instructions for use and facility protocol.
m - Advance the catheter and stylet. As the stylet tip approaches the **Sherlock** sensor module, the cursor will indicate where the stylet tip is located in relation to the sensor module.

n - Monitor the location of the stylet tip icon along the **Sherlock** sensor module. The icon will show the direction of the catheter as it progresses through the venous system. Adjust catheter position as necessary until the icon shows the catheter progressing down into the SVC.

10 - As the stylet approaches the **Sherlock** logo located at the lower third of the sensor module, an audible / visible indicator provides location feedback to the clinician.

Note: To mute the detector: Press the mute button. You cannot adjust the volume of the detector.

Note: The stylet icon is displayed in its relative position to the sensor module as if viewed from above the sensor module.

11 - When the stylet icon is in the desired position, the **Sherlock** detector can be powered down or remain operational for the remainder of the procedure.

12 - Complete catheter insertion and securement procedure according to the catheter instructions for use and facility protocol.

13 - Remove the sterile field.

14 - Remove the sensor holder pouch and adhesive.

15 - Open the sensor holder pouch and remove the **Sherlock** sensor module.

16 - Dispose of the sensor holder pouch in accordance with facility policy.

Note: The sensor holder pouch is for single-use only.

17 - Follow facility protocol to confirm final catheter tip location.

7] Troubleshooting

Problem	Solution
The **Sherlock** detector won't power on.	Press and hold the power button for at least 3 seconds
The **Sherlock** detector won't power on, or powers on but immediately turns off.	Attach the AC adaptor to both power the **Sherlock** during the procedure, and to charge the battery. Plug the AC adapter into the screen module.
When the Start/Calibration button is pressed, the Attach Sensor Module screen is displayed.	Make sure the sensor module cable is inserted fully and correctly into the display module. Press the Start/Calibration button to begin again. If the Attach Sensor Module screen still appears, contact Bard Access Systems customer service at 1-800-545-0890.
When the Start/Calibration button is pressed, the Magnetic Field Error screen is displayed.	Lower bed rails. Make sure all metal objects are at least 30 cm [12 in] from the sensor module. Make sure the sensor module pouch is firmly attached and ask the patient to remain still during the calibration process and during catheter insertion. Press the Start/Calibration button to begin again.

Problem	Solution
During catheter insertion, the Magnetic Field Error screen is displayed.	Make sure no metal objects have been brought near to the sensor module Make sure the sensor module pouch is firmly attached and ask the patient to remain still during catheter insertion. Press the Start/Calibration button to begin again.
The Internal Error screen is displayed during **Sherlock** power-on, or at any other time while in use.	Press and hold the power button to turn off the system. Power the system back on and if the Internal Error screen is no longer displayed, proceed as normal. If the Internal Error screen is again displayed, contact Bard Access Systems customer service at 1-800-545-0890.
Sensor does not detect stylet.	Check stylet to verify magnetic tip has not been trimmed off. Check stylet to insure tip is within one cm of catheter end. Reposition sensor to clavicle as described in Step 3 -9, page 18.

8] Maintenance

1 - Wipe the **Sherlock** display and sensor modules after each use according to facility protocol.

Caution: Do not submerge the **Sherlock** screen or sensor modules in water or other fluids or attempt to sterilize. Do not open or attempt to open the **Sherlock** modules as they are not user serviceable. Contact Bard Access Systems for service returns.

2 - Battery Life

a - The runtime of a fully charged battery is approximately 4 hours.

b - If the **Sherlock** sensor module does not sense a **Sherlock** stylet after 30 minutes, the **Sherlock** detector will automatically power off.

c - Low battery charge is indicated on the screen module by the flashing battery icon.

d - When battery power is low, the AC adaptor can be used during catheter placement.

e - The **Sherlock** detector can be used for approximately 20 minutes after the low battery power indicator (flashing battery icon) is first displayed.

f - To recharge the battery fully, connect the AC adaptor to the **Sherlock** screen module. The battery power indicator on the screen module will display bars to represent the amount of charge the battery received. To fully recharge the battery, plan on a minimum of 3 hours.

To store the **Sherlock** device: The **Sherlock** sensor and screen module may be placed in the carrying case for secure transport. The detector should be operated at temperatures from 10° C (50° F) to 40° C (104° F). The **Sherlock** detector should be stored at temperatures from 0° C (32° F) to 60° C (140° F). If the **Sherlock** detector is stored at temperatures outside of the operating range, the detector should be allowed to stabilize for two hours prior to operation in the operating temperature range.

9] Specifications

1 - Power source: Lithium polymer battery or 120V AC power supply

2 - Usable runtime of a fully charged battery under continuous use: Approximately 4 hours

3 - Controls:
a - Power – ON/OFF button
b - Mute/No Mute button
c - Start – Start/Calibration button

4 - Display Screen Information:
a - Start-up Screen
b - Start/Calibration
c - Calibrating
d - Ready for Use
e - Stylet Tip Position
f - Mute/No Mute
g - Battery Charge
h - Low Battery
i - Magnetic Error
j - Internal Error

5 - Cables:
a - AC adaptor – power source for the **Sherlock** detector
b - Extension cable – connects the sensor module with the screen module. It is detachable from the screen module

Appendix A: **Sherlock** Tip Location System - Electromagnetic Compatibility

A.1 COMPLIANCE AND WARNINGS

The BARD **Sherlock** Tip Location System has been tested to and found compliant with the requirements of IEC 60601-1-2:2001

Warning
The use of other accessories other than those specified may result in increased emissions or decreased immunity of the equipment

Verify correct operation if the **Sherlock** TLS is to be used adjacent to other equipment.

A.2 ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The **Sherlock** detector is intended for use in the electromagnetic environment specified below. The customer or the user of the **Sherlock** detector should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The **Sherlock** detector uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions	Class A	The **Sherlock** detector is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Essential Performance
The **Sherlock** detector maintains safe and effective performance of the catheter tracking function when operated in the electromagnetic environment specified in Tables A-2 through A-4.

Limitations Affecting Immunity to Electromagnetic Disturbances
The level of protection from electromagnetic disturbances is limited by several factors, including requirements for patient safety isolation, and maintenance of adequate signal-to-noise ratios for processing of magnet tipped stylet signals.

A.3 ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity			
The **Sherlock** detector is intended for use in the electromagnetic environment specified below. The customer or the user of the **Sherlock** detector should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The **Sherlock** detector is suitable for use in a dry environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC60601 test level	Compliance Level	Electromagnetic environment - guidance
Surge IEC 61000-4-5	± 1 kV differentia mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % *UT* (> 95 % dip in *UT* for 0,5 cycle) 40 % *UT* (60 % dip in *UT* for 5 cycles) 70 % *UT* (30 % dip in *UT* for 25 cycles) < 5 % *UT* (> 95 % dip in *UT* for 5 seconds)	< 5 % *UT* (> 95 % dip in *UT* for 0,5 cycle) 40 % *UT* (60 % dip in *UT* for 5 cycles) 70 % *UT* (30 % dip in *UT* for 25 cycles) < 5 % *UT* (> 95 % dip in *UT* for 5 seconds)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Sherlock** detector requires continued operation during power mains operation, it is recommended that the **Sherlock** detector shall be powered from an uninterruptible power supply or battery.
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *UT* is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The **Sherlock** detector is intended for use in the electromagnetic environment specified below. The customer or the user of the **Sherlock** detector should assure that it is used in such an environment.			
Emissions Test	Compliance	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **Sherlock** detector, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz

Emissions Test	Compliance	Compliance Level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and poles

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Sherlock** detector is used exceeds the applicable RF compliance level above, the **Sherlock** detector should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Sherlock** detector.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A.4 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the **Sherlock** detector

The **Sherlock** detector is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Sherlock** detector can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Sherlock** detector system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance of the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of this device. RFI may result in improper device operation or failure to detect a correctly placed catheter. Avoid operating the device near cauterizers, diathermy equipment, cellular phones, or other portable and mobile RF communications equipment. Maintain equipment separation of at least 1.2 m (4 ft) and do not rapidly key radios on and off. Contact a technical support representative if assistance is required.

Possible electrical interference.
Using cables, battery chargers, or accessories not specified for use with this device may result in increased emissions or decreased resistance to electromagnetic interference, which could affect the performance of this device or of equipment in close proximity. Use only parts and accessories specified in these operating instructions.

Safety Information

WARNINGS!

Possible device shutdown.
Always check to make sure the battery is properly charged prior to the start of any procedure. Recharge the battery after each use and when the device displays a low battery warning.

Possible improper device performance.
Using other manufacturers' cable, battery, or battery charger may cause the device to perform improperly and invalidates the safety agency certification. Use only the accessories specified in these Operating Instructions.

Safety risk and possible equipment damage.
The **Sherlock** detector and accessories contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. Consult the MRI manufacturer for more information.

CAUTION!
Possible equipment damage.
This device may be damaged by mechanical or physical abuse such as immersion in water or dropping the device. If the device has been abused, remove it from use and contact the manufacturer.

Safety risk and possible equipment damage.
The **Sherlock** detector Tip Location System AC adaptor and power cord is specifically designed for use with the **Sherlock** detector. Use of any other power supply may cause damage to the system, or harm to the operator or patient. Use only the **Sherlock** detector AC adaptor, BARD PN 9760062, and the **Sherlock** Power Cord, BARD PN 9760065 with the **Sherlock** detector Tip Location System.

Warning: Refer to Manual Before Use

BF Type Equipment

Do Not Dispose of Battery Pack In Fire

Do not operate in the presence of flammable anesthetics.

Canadian Standards Association

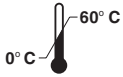
Class II Insulation

Federal Communications Commission

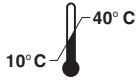
Do not dispose with ordinary municipal waste

℞ ONLY Prescription Only

Battery Pack



Storage Temperature Parameters



Operating Temperature Parameters

Operating Humidity

Storage Humidity

Latex Free

Sherlock* Tip Location Detector Manufactured for:

Bard Access Systems
Salt Lake City, UT 84116
U.S.A.

(801) 595-0700
Customer Service: (800) 545-0890
Technical/Clinical Information: (800) 443-3385
Fax: (801) 595-4948
www.bardaccess.com
www.Discover**Sherlock**.com